Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12485

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[redacted]

TRIAL LAWYERS

[redacted]

[redacted]

97-256

RECEIVED
JUL 30 1997
FDA FOI STAFF (HFI-35)

July 25, 1997

FREEDOM OF INFORMATION
Food & Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, Maryland 20857

Re: Freedom of Information Act Request and Product Complaint
Product Name: "Ripped Fuel " (MaHuang/Ephedrine)
Complaint: Ingestion Resulting in Death (Fatal Arrhythmia/30 Y/O Male)

Dear Sir or Madam:

The purpose of this letter is to lodge a complaint with the FDA regarding the product known as "Ripped Fuel" manufactured by Twin Labs of N.Y., which contains "MaHuang extract" (Ephedrine) and "Guarana extract" (Caffeine) and is marketed as a metabolism enhancer and fat burner.

This firm has been retained by the widow and surviving minor daughter of the late [redacted] who died of a sudden and fatal cardiac arrhythmia after ingesting the subject product and returning from jogging.

Enclosed please find a copy of the initial coroner's report and the supplemental report done at the request of decedent's physician (after he had reviewed the initial coroner's report and was perplexed as to its findings).

Upon further inquiry to the decedent's widow, Dr. [redacted] discovered the decedent's use of the product known as "Ripped Fuel" and that it contained extract from the Chinese Herb known as MaHuang (ephedrine). It was at that point, Dr. [redacted] requested further investigation by the coroner which resulted in the attached supplemental report.

Based thereon, Dr. [redacted] is firmly of the opinion that the subject product was the medical cause of Mr. [redacted] sudden and untimely death and has agreed to so testify, if necessary.

Therefore, please accept this letter as a formal complaint by Mrs. [redacted] relative to this product.

[redacted]

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[redacted]

[redacted]

Further, please also accept this letter as a request under the Freedom of Information Act for copies of any information or investigative materials derived from investigations conducted by the FDA, to date, regarding this product.

Please also be advised that we have retained and have in our possession all of the "Ripped Fuel" capsules in their original container which remained after the decedent took his last dosage the morning of his untimely death.

We are interested in having a random sampling of these remaining capsules analyzed to determine their actual chemical content and actual concentration of ephedrine, caffeine and/or other relevant ingredients.

If the FDA conducts such testing and analysis as part of its public functions or investigations, please advise as we would like to have the FDA conduct such analysis/testing as soon as possible.

Finally, we have filed a civil wrongful death action against Twin Labs and others involved in the chain of production and distribution of the subject product; A copy of which (First Amended Complaint) is enclosed for the FDA's information.

Thank you for the FDA's attention and anticipated response to this product complaint and request for information, both of which are of grave concern to the widow and surviving minor daughter of the late [redacted]

Sincerely,

[redacted]

[redacted]

Enclosures
cc: [redacted]
cc: [redacted]

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Rec CRRS
8/18/97

Adverse Reaction Questionnaire

Complaint Number: CFSAN Project #12485 Investigator: Nianna M. Capalia

Consumer Information

Date of Report: 8/27/97 (MM/DD/YY)

Initial Report Source: ☐ORA Consumer Injury
☐Telephone ☒Correspondence ☐MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted] Gender: ☐F ☒M Age: 38

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other _____ ☐9-Unknown

Information on Adverse Reaction

Date of Adverse Reaction: 6/6/96
Previous Reaction to Product Type: ☐Yes ☒No

Give the site of consumption/ingestion (e.g. home, restaurant, office): Home

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):

(Please see attached sheet)

How long did the symptoms last?
Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.).

(Please see attached sheet)

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:

(Please see attached sheet)

Did event abate after use of suspected product stopped or dose reduced: ☐Yes ☐No ☒Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☒Unknown ☐Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☒Unknown ☐Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No
Give health care provider's name, address and telephone number: (Please see attached sheet)

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist
☐Other (specify) _____

What medical tests were performed and what were the results? (Please see attached sheet for this section)

What was the medical diagnosis?
What treatment(s) was given (e.g., drugs, other)?

Were there any preexisting condition(s)/treatment(s)?
(If YES, list them including allergies, and chronic diseases): ☒Yes ☐No (Please see attached sheet)

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Product Category

1. Adverse reaction to:
   - ☐ Medical Food (under medical supervision)
   - ☐ Infant Formula
   - ☒ Dietary Supplement (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe, amino acids; extracts from animal glands, garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
   - ☐ Other (traditional food) _____

Other Product Problems

2. ☐ Foreign Object (specify): _____
3. ☐ Other (specify): _____

Information on Suspected/Alleged Product

Give the product name as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

(Please see attached sheet)

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):

☐ Check here if ingredients are unknown

(Please see attached sheet)

If a particular ingredient is suspected of contributing to the reaction, please indicate the appropriate category below:

- ☐ Aspartame
- ☐ Monosodium Glutamate
- ☐ Sulfite
- ☒ Other MaHuang Extract (Please see attached sheet)
- ☐ Unknown
- ☐ Color Additive (please specify) _____

Is the product label available, if yes submit a quality copy along with this questionnaire: ☒ Yes ☐ No ☐ Unknown

Product Sample Available: ☒ Yes ☐ No ☐ Unknown

Sample submitted to SEA-DO as CR#97-790-066 (copy attached)

Outcome Attributed to Adverse Event:

(If yes, include pertinent medical records)

Death: ☒ Yes ☐ No

Life-Threatening: ☒ Yes ☐ No

Hospitalization: ☐ Yes ☐ No (if YES, indicate if initial or prolonged) Pronounced dead at Emergency Room.

Required intervention to prevent permanent impairment/damage: ☐ Yes ☐ No N/A

Did the adverse reaction result in a congenital anomaly: ☐ Yes ☐ No

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Adverse Questionnaire (IOM Exhibit 910-D) - Additional Comments

Complaint Number: CFSAN Project #12485
Investigator: Nianna M. Capalia
Date: August 28, 1997

*The following comments correspond to questions listed in the Adverse Questionnaire.

Information on Adverse Reaction

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):

The following information is what I learned from Mr. [redacted] attorney for Ms. [redacted] Ms. [redacted] is widow to Mr. [redacted] who died after ingesting TWINLAB® Metabolic Enhancer Ripped Fuel.

On the morning of June 6, 1996, Mr. [redacted] drank a cup of coffee, then ingested Ripped Fuel capsules according to bottle instructions. Mr. [redacted] then went outside for his morning jog. He started talking to his wife and daughter after returning to his home. Meantime, he did not complain of symptoms. Mr [redacted] then dropped to the floor and was having to what appeared a "grand mal seizure". The paramedics were called; when they arrived, Mr. [redacted] was on the floor in full arrest. After Mr. [redacted] was brought to the hospital, he was pronounced dead by an Emergency Room physician. Cause of death was determined as acute arythmia due to atherosclerotic cardiovascular disease.

Exhibit #1: Paramedics report and Dispatch Record from [redacted]

Exhibit #2: Autopsy Protocol and Toxicology Report under Dr. [redacted] *as Pathologist.*

How long did the symptoms last?
We do not know the answer to this question, since Mr. [redacted] did not complain until he fell to the floor, and then became unconscious until his death.

Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.)
According to Mr. [redacted] Mr. [redacted] had been taking TWINLAB® Metabolic Enhancer Ripped Fuel for approximately the past year. From a doctor's visit approximately a year ago, the doctor suggested that Mr. [redacted] lose weight. Within the past year, Mr. [redacted] regularly excercised and regularly ingested Ripped Fuel according to directions. The labeling of the bottle with the capsules I collected read in part: "As a dietary supplement, take 2 capsules before morning workout on an empty stomach. Also, take 2 capsules before afternoon and evening meals." The morning of his death, Mr [redacted] had a cup of coffee, and then two capsules of Ripped Fuel, followed by jogging outside.

List all Medication(s), Dietary Supplements(s), Food(s), and other product(s) used <u>at the time</u> of the event:
It is believed that no other medications or diet products (other than Ripped Fuel) were taken. Ms. [redacted] believes that her husband was taking multi-vitamins at the time of his death; however it is not recalled which kind they were. Ms. [redacted] advised, that as far as she knew, Mr. [redacted] had never experienced adverse reactions to any other medications or food products.

Exhibit #3: Fax from Ms. [redacted] Secretary to Mr. [redacted] The fax addresses the question of whether Mr. [redacted] took other medications, dietary supplements, foods, and other products near the time of death.

Medical Information

Give health care provider's name, address, and phone number:
1. [redacted] by Paramedics [redacted] and [redacted]
(Record as seen in Exhibit #1)
[redacted]
(Since 6/10/96, [redacted] has changed their company name to [redacted] and now to [redacted]
2. [redacted] M.D. , Pathologist (See Exhibit #2)
[redacted]
3. Dr [redacted] regular attending physician.
[redacted]

What medical tests were performed and what were the results?
See above Autopsy Protocol and Toxicology report under Exhibit #2.

Where there any preexisting condition(s)/treatment(s)?
Yes, there were prexisting conditions:
1) There is mention of "...history of heart problems." (See Autopsy Protocol, Exhibit #2, 1st paragraph, 4th line)
2) "According to the decedent's wife, the decedent had been treated for pneumonia a few times and it was stated that he had some sort of "build up" around his heart" (Same Exhibit, all of 3rd paragraph)
3) According to Mr. [redacted], Mr. [redacted] took the product to assist him in losing 40-50 pounds during the course of the year. Mr. [redacted] is not aware of any complaints, prior problems, or mental health history.

Information on Suspected/Alleged Product

Give the product name as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

The following information is provided on the label. The label is black in color with white and red print.

"TWINLAB® Metabolic Enhancer Ripped Fuel***Thermogenic Formula***60 capsules***"

RECOMMENDED USE: As a dietary supplement, take 2 capsules before morning workout on an empty stomach. Also, take 2 capsules before afternoon and evening meals. Do not exceed 6 capsules daily. Taking more than the recommended amount will not improve results and may cause adverse reactions listed in the warning below. Begin use with one-half of the recommended dose (one capsule three times per day) to assess your tolerance. For best results, use as part of a low fat diet and excercise program. Please note: Guarana extract contains caffeine and should not be taken by those wishing to eliminate caffeine from the diet.

WARNING: Do not use if you are pregnant or nursing or if you are at risk or are being treated for high blood pressure, heart, liver, thryroid or psychiatric disease, diabetes, pernicious anemia, nervousness, anxiety, depression, seizure disorder, stroke or difficulty in urination due to prostate enlargement. Consult your health care professional before use if you are taking an MAO inhibitor or any other prescription drug. Discontinue use and consult your health care professional if dizziness, sleeplessness, tremors, nervousness, headache, heart palpations or tingling sensations occur. NOT INTENDED FOR USE BY PERSONS UNDER THE AGE OF 18. KEEP OUT OF REACH OF CHILDREN.

Two Capsules Provide:	Ma Huang Extract...334mg (standardized for 6% ephedrine) Guarana Extract...910mg (standardized for 22% caffeine) L-Carnitine...100mg Chromium...200mcg (from Chromic Fuel® patented chromium picolinate) *No U.S. RDA established

WARNING: Diabetics may use only under a physician's supervision because this product contains chromium picolinate which may enhance insulin sensitivity.

Lot number seen on neck of bottle and not on label reads: "Lot #56491"

Exhibit #4: *Photocopy of TWINLAB® Metabolic Enhancer Ripped Fuel taken at Mr. [redacted] office, by his secretary, Ms.* [redacted]

Exhibit #5: *Mrs.* [redacted] *receipt, listing 4/25/96 and* [redacted] *as the supposed date and location she purchased the Ripped Fuel.*

If a particular ingredient is suspected of contributing to the reaction, please indicate the appropriate category below:
Other: MaHuang Extract.
The comments section for Dr. [redacted] Autopsy Protocol (Exhibit #1) states: "Ephedrine is a stimulant medication, and as such may have contributed to a fatal arrhythmia in the decedent."

Other Exhibits
Exhibit #6: *Copy of Original CFSAN Assignment*

[redacted]

TRIAL LAWYERS

[redacted]

[redacted]

August 27, 1997

VIA FACSIMILE & U.S. MAIL

Nianna M. Capalia
U.S. FOOD AND DRUG ADMINISTRATION
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Re: [redacted] v. Twin Laboratories, et al.
Decedent: [redacted]

Dear Ms. Capalia:

In follow-up to your meeting of August 25, 1997 with Mr. [redacted], enclosed please find a copy of the paramedic records of [redacted] We are also enclosing a copy of a [redacted] Visa statement showing the [redacted] purchase of 4/25/96. Mrs. [redacted] will be further checking her records to see if she has an actual store receipt for the Ripped Fuel product, and we will forward that to you if she is able to locate same.

In response to your other inquiries, Mrs. [redacted] has advised that her husband was not taking any other medications or diet products (other than the Ripped Fuel), and she believes her husband was taking multi-vitamins at the time of his death; however, she does not recall what kind they were. She also advised that as far as she knew, he had never experienced adverse reactions to any medications or other food products.

If there is anything else you need at this time, please do not hesitate to give me a call.

Very truly yours,

[redacted]

By: [redacted]

[redacted]
Enclosures